osteopore

MAR 17 2006

958 Kristin Ridge Way
Milpitas CA 95035

510 K SUMMARY (K051093)

Proprietary Name:	Osteopore PCL Scaffold Bone Void Filler (BVF)	
Common Name:	Bone Filler	
Classification Name:	GXP	
Predicate Device/Material	PCL Monofilament Surgical Specialties Absorbable Suture	K003015
	WMT-TCP	K022629
	ChronOS	K013072
	Ethicon's Monocryl(Poliglecaprone 25) E caprolactone/Glycolide 510 (k)	K930772
	U.S. Surgical's Caprosyn (Polyglytone 6211) Glycolide, caprolactone.trimethylene carbocarbonate and lactide 510 (k)	K013671
	CAP BONE SUBSTITUTE MATERIAL	K032307
Device Sponsor:	Osteopore Inc 958 Kristin Ridge Way Milpitas CA 95035	
Manufacturer:	Osteopore International Pte Ltd 10 Science Park II #02-28 The Alpha Singapore 117684	
Official Correspondent:	Alexander Yeo	

Device Description:

The Osteopore PCL Scaffold™ is a bone void filler. The shape of the Osteopore PCL Scaffold™ conforms to the defect, thus maximizing direct contact with viable host bone.

Intended Use:

The Osteopore PCL Scaffold™ Bone Filler is intended for use in the repair of neurosurgical burr holes, craniotomy cuts and other cranial defects. It is also for use in the augmentation or restoration of bony contour in the craniofacial skeleton. It should be gently packed into bony voids or gaps of the skeletal system.

Evaluation of Device

Osteopore PCL Scaffold™ was evaluated for performance using a rabbit calvarial defect model. The study demonstrated safety and efficacy of the Osteopore PCL Scaffold for the intended use.

Summary of substantial equivalence

The Osteopore PCL Scaffold™ shares indications and design principles with the following predicate devices, PCL Monofilament Surgical Specialties (K003015) and Absorbable Suture WMT-TCP (K022629), which have been determined by the FDA to be substantially equivalent to pre-amendment devices. The Osteopore PCL Scaffold™ shares the same material biocompatibility, cytotoxicity, genotoxicity, sensitization, chronic toxicity and carcinogenicity as FDA cleared suture products. Osteopore scaffolds are made initially from filaments which are equivalent to FDA cleared suture devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 17 2006

Mr. Alexander Yeo
Osteopore, Inc.
958 Kristin Ridge Way
Milpitas, CA 95035

Re: K051093
Trade/Device Name: Oseopore PCL Scaffold Bone Void Filler
Regulation Number: 21 CFR 882.5300
Regulation Name: Methyl methacrylate for cranioplasty
Regulatory Class: Class II
Product Code: GXP
Dated: December 15, 2005
Received: December 19, 2006

Dear Mr. Yeo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

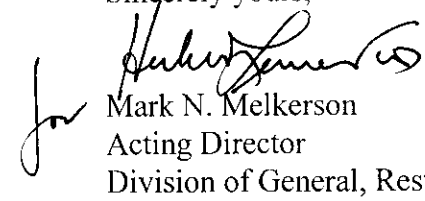
You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice

requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Acting Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

osteopore

958 Kristin Ridge Way
Milpitas CA 95035

INDICATIONS FOR USE

510(K) Number K051093:

Device Name: **Osteopore PCL Scaffold™ Bone Void Filler**

Indications for Use:

The Osteopore PCL Scaffold™ Bone Filler is intended for the use in the repair of neurosurgical burr holes, craniotomy cuts and other cranial defects. It is also for use in the augmentation or restoration of bony contour in the craniofacial skeleton.

Prescription Use ____X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K051093